Guidelines for the Risk-Based Good Clinical Practice Audits was Published by the Ministry of Health

28 Oct 2022

Turkish Pharmaceuticals and Medical Devices Agency ("**TITCK**") Medicine Audit Agency published the Guideline for the Risk-Based Good Clinical Practice Audits ("**Guideline**") on 8 August 2022.

The Guideline aims to define and standardize the processes related to risk-based good clinical practice ("**GCP**") audits.

The most remarkable matters within the scope of the Guideline are as follows:

- The Guideline covers the clinical trials presented in the registration application, including the bioavailability / bioequivalence studies, the ongoing clinical trials, and the institutions, organizations and individuals related to these trials.
- Pursuant to the Guideline; GCP audits can be conducted for the verification of the application for registration, or for a follow-up after registration before, during or after the clinical trial is conducted.
- Any clinical research included in the license application file can be subject to audit, in this way, a GCP audit can be carried out for a specific reason or within the scope of a routine audit.
- The provisions of "Guideline on Triggers for Routine and/or for Specific Reason Inspections" and the "Guideline on Triggers for Inspections of Bioavailability / Bioequivalence Studies" will also be taken into consideration in GCP inspections to be carried out within the scope of the Guideline. You can reach our article, published in MA | Gazette dated 29 April 2022 and numbered 115, about these guidelines from this
- The Guideline states that license application, clinical research and clinical research centers can be selected for inspection in routine GCP inspections.
- Inspections for a specific reason can be requested by the evaluators due to a concern about deviations from the GCP in all clinical trials conducted with a human medicinal product or in studies conducted at a specific center during the evaluation process of the marketing authorization application.
- In the GCP audits performed within the scope of routine audits, the sponsor, contractual research institution, researcher and / or other relevant parties within the scope of the research could be informed before the planned audit date, whereas in the audits for a specific reason, a prior notice can be given, or the audit can be carried out without notice.

You can access the full text of the Guideline via this link. (only available in Turkish.)

Related Attorneys

- I?IK ÖZDO?AN, LL.M.
- SENA YA?ARO?LU